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10/523,529	08/11/2005	John F Wetling	36731-000052/US	1446

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EXAMINER

PATTON, AMANDA K

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3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,529	Applicant(s) WETLING, JOHN F	
	Examiner Amanda Patton	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 12-16 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10, 12-16 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/4/9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2008 has been entered. Currently claims 7-10, 12-16, and 20 are pending in this application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

However, disclosure of the invention in the foreign priority application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, PCT/DK03/00523 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claims 7-10, 12-16, and 20 are not supported by either the prior filed application or the presently filed application as further detailed below.

Claims 12-13 are not supported by the prior filed application, as there is no mention of “electrically isolating the patient from ground” or “spraying an area of a patient with ions”.

Specification

The disclosure is objected to because of the following informalities: The specification, as currently amended, does not adequately describe the claimed invention of claims 7-10, 12-16, and 20. For example, the specification does not disclose the following structural and method step limitations:

- "feedback unit is adapted to keep the objected at a specific potential" as required by claim 7, lines 8-9;
- "wherein the feedback unit is adapted to monitor a number of discharged ions per unit of a time measure" of claim 8, lines 1-2;
- "wherein the feedback unit is adapted to monitor a total charge delivered to the object" of claim 9, lines 1-2 and claim 14, lines 1-2;
- "wherein the feedback unit is adapted to monitor a time measure for an exposure of ions by the object" of claim 10, lines 1-2, claim 15, lines 1-2, and claim 16, lines 1-2;
- "electrically isolating the patient from ground" of claim 12, line 3;
- "maintaining the object at a specific potential" of claim 12, line 6;
- "further including positioning the patient in a vertical or horizontal position on an insulating cover" of claim 13, lines 1-2 and "wherein the insulating cover is adapted to carry the object in a horizontal or a vertical orientation" of claim 20, lines 1-2 (a horizontal position is shown in Figure 5, but no vertical position is described or shown in the specification).

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If applicant believes these structural and method step limitations are included in the specification, citation of the specific portion of the specification where there are found is requested. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-10, 14-16, and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 7, line 3 appears to be positively claim connection to the human body. It is suggested to replace the word “attached” with “attachable” so that there is no positive claim to a human body and no claim of connection to the human body.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10, 12-16, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7, lines 8-9 recite the phrase “adapted to maintain an electrical potential of the object to be treated” and Claim 12, line 6 recites the phrase “maintaining the

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object at a specific potential". which does not find support in the specification as originally filed. Thus it is unclear how the feedback unit is adapted to keep the object at a specific potential" as no adequate accompanying description is given.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10, 14-16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, lines 5-7 recite a feedback unit, but do not disclose how the feedback unit controls the exposure and dose of ions given to the object being treated, as the feedback unit is not capable of sensing any parameter as presently filed.

Claim 7, line 3 recites "an object". It is unclear if the "object" is being functionally or positively recited. It is suggested to replace the word "attached" with "attachable" so that there is no positive claim to a human body and no claim of connection to the human body.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, 12-16, and 20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gisel (USPN 6,549,808, as previously cited).

Regarding **claims 7, 9, 12, and 14**, Gisel et al. disclose a negative ion generator, an electrical cable adapted to be placed between a feedback unit and an object to be treated, (e.g., FIGS. 1-5; ABSTRACT, lines 11-14), a feedback unit (e.g., element 52, regulator) and an insulating cover (e.g., element 18, flexible plastic material); electrically isolating a patient (e.g., column 3, lines 21-23; column 5, lines 7-9); spraying an area of a patient with ions (e.g., ABSTRACT, lines 11-14; column 3, lines 25-26 and 36-38), wherein feedback unit is adapted to keep the object at a specific potential (e.g. column 3, line 33).

It is the Examiner's position that the insulating cover of Gisel is capable of being placed beneath the object being stimulated, as the term "beneath" is a relative term. If the patient was lying on their stomach the insulating cover would be beneath the patient.

It is also the Examiner's position that the feedback unit of Gisel is located in between the power unit (e.g. battery 40) and the object (e.g. electrodes 20 and 22 connected to the patient) and is capable of controlling an exposure and dose of ions to the object being treated, as the

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providing of an increased voltage differential IS controlling the exposure and dose of ions to the object being treated and keeping it at a specific potential as directed by the user. As the device is capable of controlling an exposure and dose of ions to the object being treated as well as the amount of time of treatment (e.g. Col. 5, lines 35-36), it necessarily is able to monitor the total charge delivered to the object.

In the alternative, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method as taught by Gisela with a separate feedback unit located between the power unit and the object, because Applicant has not disclosed that this arrangement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the feedback as taught by Gisela, because it provides a reliable feedback unit and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Gisela. Therefore, it would have been an obvious matter of design choice to modify Gisela to obtain the invention as specified in the claims.

Regarding **claims 13 and 20**, the orientation of Gisela can be considered vertical or horizontal relative to the insulating cover.

Regarding **claims 8, 10, 15 and 16**, Gisela et al. disclose monitor a number of discharged ions per unit of a time measure (e.g., column 3, lines 39-41; column 5, lines 35-37).

Response to Arguments

Applicant's arguments with respect to claims 7-10, 12-16, and 20 regarding Copus have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 7-10, 12-16, and 20 regarding Gisel have been considered but are not persuasive, inasmuch as they apply to the rejections above necessitated by the amendments to the claims. In particular, Examiner asserts that as each electrode of Gisel is held at the same potential they are maintained at a specific potential. Applicant has not provided any support from the specification to show how the present invention is different from the invention of Gisel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762